Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/601,844	REDDY ET AL.	
	Examiner	Art Unit	
	PAUL V. WARD	1624	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 July 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-18*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment below.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/James O. Wilson/
Supervisory Patent Examiner
Art Unit 1624

102(b): Applicant claims amorphous levocetirizine dihydrochloride, amorphous levocetirizine dihydrochloride free of crystalline forms of cetirizine dihydrochloride, and compositions comprising the levocetirizne dihydrochloride. Additionally, Applicant claims compositions of levocetirizine dihydrochloride containing a moisture content ranging from about 0.3 % to 12% using the KF method.

Tang teaches the exact amorphous levocetirizine dihydrochloride and falls within the range of Applicant's compounds. (See Abstract, pg. 311, Fig. 1 pg. 311, and Figures 2-3 on pg. 312). Since Tang teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

Pflum teaches the exact amorphous levocetirizine dihydrochloride and falls within the range of Applicant's compounds. (See Abstract, pg. 110, Fig. 1 pg. 110, and Tables 2-3 on pg. 111 and left col.). Additionally, on page 111, left hand column, and on page 112, right hand column (last paragraph), Pflum teaches that the levocetirizine contain yields of 79% and 99%. Since Pflum teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

Van de Venne teaches compositions comprising levocetirizine dihydrochloride with one or more pharmaceutically acceptable excipients, and falls within the range of Applicant's compounds. (See Abstract, col. 3 lines 45-60, col. 5, lines 10-55, and Table in col. 6). Since Van de Venne teaches the exact compositions, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

103: Van de Venne teaches compositions comprising levocetirizine dihydrochloride (See Abstract and columns 3-6). The claims differ from the reference by reciting the composition containing a moisture content.

Thus, Van de Venne does not teach Applicant claims in the same format as claimed by applicant, however, one skilled in the art would find the differences in the teaching to be negligible. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Van de Venne to obtain the compositions as claimed in the instant application. Obviousness based on similarity of structure and functions entails motivation to make the clamed compound in expectation that compounds similar in structure will have similar properties. Therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for levocetirizine compositions. See In re Payne, 203 USPQ 245 (CCPA 1979). Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

Applicant argues that the prior art does not disclose "amorphous" levocetrizine dihydrochlorides.

The amorphous form is an obvious variation, which one is motivated to obtain because of the expected solubility advantage. Note this from the conclusion of Hancock, Pharm. Res. 17(4) 397 (2000): "Amorphous pharmaceuticals are markedly more soluble than their crystalline counterparts…Based on a comparison with polymorphic crystal forms of drug compounds the clinical relevance of solubility increases for amorphous drug forms is likely to be significant, even in systems which are only partially amorphous.

Thus, Applicant arguments are not persuasive. Therefore, the rejection of claims 1-18 under 35 U.S.C. 102, 103 and 112, set forth in the Office action dated November 17, 2006 has been maintained for the reasons of record for the reasons set forth herein.